

## REMARKS

This Response is made in response to the Office Action dated July 8, 2009. Claims 64 - 84 are pending in the present application. Reconsideration of the application is respectfully requested in view of the remarks below.

The Examiner rejected claims 64, 65, 67-76 and 78-83 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,120,308 to Hess (the "Hess patent"). Applicants respectfully disagree with the Examiner's position regarding the disclosure found in the Hess patent. The Examiner takes the position that the plurality of tapered segments disclosed in the Hess patent produce a substantial linear change in bending stiffness over the length of the member and that bending stiffness is directly proportional to cross sectional area. However, Applicants respectfully note that the Examiner does not cite to any disclosure in the Hess patent to support this statement. Applicants submit that the mere presence of a plurality of tapered segments in a guide wire does mean that there is a substantially linear change in bending stiffness over the length of the guide wire. Applicants' presently claimed invention does not simply recite an elongated member having a plurality of tapered segments. Rather, claim 64 requires an elongated member having a longitudinal length and **means for causing a substantially linear change in bending stiffness over the entire longitudinal length of the elongated member**. In claim 64, those means are a plurality of tapered segments **configured to produce** the substantially linear change in bending stiffness over the length of the member. The Hess patent fails to disclose this particular structure.

Upon careful review, Applicants note that the Hess patent does not contain any disclosure of an elongate member having a linear change in stiffness as is recited in the present claims. The tapered sections of the guide wire in the Hess patent are described as follows at Column 7, line 65 to Column 8, line 3:

FIG. 1 shows the detailed structure of the guide wire 14 wherein the guide wire is non-uniform in cross-section. Specifically, guide wire 14 preferably comprises a plurality of tapered sections 16, 18 and 20. Although three

sections are shown, it is understood that any number of sections and/or a continuous taper are within the scope of the invention.

There is no mention in the Hess patent with respect to these tapered sections 16, 18 and 20 that these tapered segments are **configured to produce** the substantially linear change in bending stiffness over the length of the guide wire. Tapered segments are also addressed with respect to an embodiment disclosed in FIG 8. Here, the Hess patent states the following at Column 9, lines 60-66:

The high flexibility of the extension wire, which preferably has a plurality of tapered sections 50, 52 and 54, provides variable strength along the length thereof from greater to lesser strength extending away from the distal end of the hollow body portion 46 to provide trackability, pushability and flexibility of the guide wire.

Again, there is no mention in this passage of the Hess patent that these tapered sections 16, 18 and 20 are **configured to produce** the substantially linear change in bending stiffness over the length of the guide wire. While these tapered sections in the Hess patent may be flexible, there is absolutely no indication that they are 20 are **configured to produce** the substantially linear change in bending stiffness over the length of the guide wire.

The Hess patent also states the following at Column 6, lines 63-69:

In the nickel-titanium alloys of the present invention  $f$  varies as  $E$  does not apply once bending has been initiated, as can be seen in FIG. 2. Once bending is initiated, very little additional stress is required to continue the bend. Also, since the mechanism is stress-induced martensite which occurs only "locally" in the region stressed, a non-uniform deflection can occur without the requirement of a uniform radius.

This language appearing in the Hess patent is descriptive of a phenomenon of stress induced martesite in a shape memory alloy. The present claims are not directed to this phenomenon. Applicants submits that the Hess patent simply does not disclose or suggest an elongated member having linear change in stiffness as defined in the specification of the pending application.

Applicants respectfully direct the Examiner to Applicants' Specification, particularly, Figures 11 and 12, which shows the characteristics of a conventional tapered guide wire, like the one disclosed in the Hess patent. The bending stiffness plot of Figure 12 shows how the tapered portion of a conventional guide wire **does not exhibit** a substantially linear change in bending stiffness. Please refer to the plot between points B and C which shows the characteristics of the tapered portion of the guide wire. In this region, the bending stiffness is quite steep and curved. This graph should be compared with the graph of Figure 14 which shows that the tapered portion of a guide wire made in accordance with the present invention has a substantially linear change in stiffness between point B and C.

Claim 71 recites a guidewire comprising an elongate core member with at least one longitudinal section having a tapering diameter and a substantially linear change in bending stiffness over a longitudinal length thereof and defined substantially by the formula:

$$D_L = \left[ \frac{64CL}{E\pi} + D_0^4 \right]^{\frac{1}{4}}$$

Where  $D_L$  is the diameter of the elongate core member at length L from a position of starting diameter  $D_0$ , L is a length greater than zero, E is the modulus of elasticity of the core member material, and C is a constant that depends on the boundary conditions of the longitudinal section.

Claim 78 defines a guidewire comprising an elongate core member with at least one longitudinal section having a substantially linear change in bending stiffness over a longitudinal length thereof and a moment of inertia defined substantially by the formula:

$$I_L = \frac{CL}{E} + I_0$$

Where  $I_L$  is the moment of inertia of the longitudinal section at length L from a position of starting inertia  $I_0$ , L is a length greater than zero, E is the modulus of elasticity

of the longitudinal section, and C is a constant that depends on the boundary conditions of the longitudinal section.

The Examiner acknowledges that the Hess patent does not expressly disclose the formulas set forth in claims 71 and 78, but has taken the position that the guide wire of the Hess patent is sufficient to read on these claims. However, the Examiner fails to identify any disclosure in the Hess patent which states that the guide wire has at least one longitudinal section having a tapering diameter and a substantially linear change in bending stiffness over a longitudinal length thereof. Further, the Examiner fails to identify any disclosure in the Hess patent which states that the guide wire includes an elongate core member with at least one longitudinal section having a substantially linear change in bending stiffness over a longitudinal length. The Examiner merely makes the broad statement that such a guide wire is disclosed in the Hess patent. Applicants respectfully submit that the Hess patent fails to disclose the guide wire recited in these claims. The disclosure of an anticipatory reference cannot be left to conjecture. Applicants respectfully submit that the Examiner has failed to prove a *prima facia* case of anticipation. The Hess patent should be withdrawn as an anticipatory reference and the pending claims should be allowed to issue.

In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Please charge any fees payable in connection with this response to Deposit  
Account No. 06-2425.

Respectfully submitted,  
FULWIDER PATTON LLP

/Thomas H. Majcher/  
Thomas H. Majcher  
Registration No. 31,119

THM:lm

366546.1